REMARKS

Status of the claims

In the Office Action, claims 6, 8, 9, and 15-22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Griffin et al. (U.S. Patent No. 5,834,223) as evidenced by the article by Galli et al. in view of Lenz et al. (U.S. Patent No. 4,914,040) (hereinafter "Griffin," "Galli," and "Lenz," respectively). In addition, claims 6, 8, 9, and 15-22 were rejected under 35 U.S.C. § 112 as allegedly containing new matter.

Response to rejection of claims 6, 8, 9, and 15-22 under 35 U.S.C. § 103(a) based on Griffin, Galli, and Lenz

Applicants respectfully submits that the presently claimed invention is not anticipated by or rendered obvious by the cited prior art because the cited prior art does not disclose (1) a combination of a coagulation time reagent containing an anti-phospholipid antibody capturing component and a coagulation time reagent not containing an anti-phospholipid antibody capturing component; and (2) that an anti-phospholipid can be detected by measuring a first coagulation time using the first coagulation time reagent and a second coagulation time using the second coagulation time reagent and recognizing a significant difference between the first regulation time and the second coagulation time.

The present claims recite that a first coagulation time reagent contains an anti-phospholipid antibody capturing component derived from vertebrate animals other than human that is selected from the group consisting of antibodies, plasma, serum and immunoglobulin. In

addition, a second coagulation time reagent does not contain the anti-phospholipid antibody capturing component.

Accordingly, a sample can be judged as LA positive, when the first coagulation time of the sample measured with use of the inventive reagent kit is shorter than the second coagulation time of the sample. Such a process is described on, for example, the first full paragraphs on both pages 13 and 14 of the present specification.

Griffin discloses a reagent kit for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated proteins C (APC)-resistant vector V or Va, comprising at least a first container containing a protocoagulant reagent, a second container containing factor v-deficient plasma, and a third container containing activated protein C (APC). Griffin teaches a reagent for measuring coagulation time.

However, Griffin does not disclose or teach a kit comprising a combination of two kinds of coagulation time reagents. Furthermore, Griffin also does not disclose or teach an anti-phospholipid antibody capturing component selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, where the anti-phospholipid antibody capturing component is derived from vertebrate animals other than human.

With respect to Lenz, Lenz relates to a method for the determination of a polyvalent substance using an immunoaggregate derived from non-human antibody. Lenz, however, does

not disclose or teach a coagulation time reagent containing a non-human antibody. In addition, Lenz does not disclose or teach a reagent kit comprising two kinds of coagulation time reagents.

As described above, neither Griffin nor Lenz disclose or teach a combination of a coagulation time reagent containing an anti-phospholipid antibody capturing component and an coagulation time reagent not containing an anti-phospholipid antibody capturing component.

As mentioned above, in the reagent kit of present claim 6, an anti-phospholipid can be detected by measuring the first coagulation time using the first coagulation time reagent and the second coagulation time using the second coagulation time reagent and recognizing the differences between the first coagulation time and the second coagulation time. Griffin and Lenz do not disclose or teach this aspect of the present invention.

Accordingly, Applicants respectfully submit that the presently claimed invention is not rendered obvious by the cited references. Applicant accordingly respectfully requests the reconsideration and withdrawal of this § 103 rejection.

Response to rejection of claims 6, 8, 9, and 15-22 under 35 U.S.C. § 112

Applicant respectfully submits that the phrase "anti-phospholipid antibody capturing component" does not constitute new matter because the present specification contains support for the phrase.

The position set forth in the Office Action was that the paragraph bridging pages 9-10 of the present specification can not support the phrase "anti-phospholipid antibody capturing component," found in the present claims. Applicant respectfully disagrees.

The paragraph bridging pages 9-10 reads, in part: "The at least one component selected from the group consisting of the antibodies, the plasmas, the serum, and the immunoglobulin derived from the vertebrate animals other than the humans...is contained in the inventive reagent in order to capture the anti-phospholipid antibody" (emphasis added). Accordingly, contrary to the position set forth in the Office Action, Applicant respectfully submits that the present specification clearly supports an "anti-phospholipid antibody capturing component."

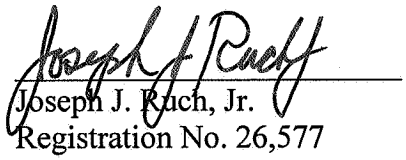
Applicant respectfully requests the reconsideration and withdrawal of this § 112 rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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